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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/146,248 09/03/98 CLEMENTE

E ASC-110.0

EXAMINER

HM12/0915

WELSH & KATZ
120 SOUTH RIVERSIDE PLAZA
22ND FLOOR
CHICAGO IL 60606-3913

SEIDLICK, R	
ART UNIT	PAPER NUMBER

1615

4

DATE MAILED:

09/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/146,248

Applicant(s)

Clemente et al.

Examiner

Brian K. Seidleck

Group Art Unit

1615



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Papers Received

1. Receipt is acknowledged of applicants' Declaration filed on 7/7/98.10/6/98.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-15 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-14 of copending Application No. **09/146,261**. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: extended release acetaminophen particles.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

6. Claims 1-15 are directed to an invention not patentably distinct from claims 1-14 of commonly assigned application 09/146,261. See above.

7. Commonly assigned application, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 13-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding the claims, it is requested that applicants recite a method of treating a febrile child instead of the present treatment for difficulty in swallowing.

10. Claim 10 recites the limitation "beads" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Patel (U.S. Pat. No. 4,867,984); Shaw et al (U.S. Pat. No. 5,773,031, collectively "Shah"); and Habib et al (U.S. Pat. No. 5,780,055, collectively "Habib").

Patel teaches a bead of a drug such as aspirin or acetaminophen formed from a small spheroidal seed particle of the drug or of an inert material coated with an adhesive and layers of drug particles likewise adhered by said adhesive, is provided. The beads may be rendered suitable

for time release by coating a plurality of said beads. An 8-12% polyvinylpyrrolidone (PVP) solution may be used as the adhesive, the PVP complexing with aspirin and acetaminophen to reduce irritation of the user. Additionally, a method for manufacturing a drug in small beads having time release properties is also provided. See abstract and claims.

Shah teaches an orally administrable sustained-release dosage form includes particles of an active pharmaceutical ingredient which is coated with a polymeric material that is water-insoluble, but water-permeable and water-swellaable, so that the sustained-release dosage form provides controlled release which is independent of certain variable physiological factors such as pH. In accordance with one aspect of the invention, the active pharmaceutical ingredient is acetaminophen and the coated acetaminophen particles are combined with uncoated acetaminophen particles to provide a combination immediate-release/sustained-release dosage form. In accordance with another aspect of the invention, the active pharmaceutical ingredient is coated with a methacrylate ester copolymer, and the coated particles are combined with uncoated particles of an active pharmaceutical ingredient to provide a combination immediate release/sustained-release dosage form, wherein the sustained-release component provides a release rate which is substantially independent of physiological factors such as pH. The final orally administrable dosage form can be appeared as compressed tablets, capsules or pouches. See abstract and claims.

Habib teaches acetaminophen in a sustained release formulation. The immediate release beads comprise sodium carboxymethyl cellulose and starch. Excipients such as magnesium

stearate are used as well as PVP. Conventional coating techniques using inert sugar cores are disclosed. The bead formulation is useful in treating febrile children or elderly in suspension form.

Thus, the prior art teaches extended release acetaminophen composition in particle form useful in treating children with fever. A blend of both immediate and sustained release particles is well known in the art to achieve both an instant relief to a patient as well as a prolonged effect over a period of 4-8 hours.

Pertinent Art

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Brian K. Seidleck** whose telephone number is **(703) 305-4448**. The examiner can normally be reached **Monday through Friday from 7:00am to 4:00pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K. Page**, can be reached on **(703) 308-2927**. The official fax numbers for Technology Center 1600 are **(703) 305-3592** and **(703) 308-4556**. The unofficial fax number is **(703) 308-7921**.

Communications via Internet e-mail regarding this application, other than those under

35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the **Technology Center receptionist** whose telephone number is **(703) 308-1235 or (703) 308-1234.**

Brian K. Seidleck
Patent Examiner
September 14, 1999

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600